IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOSTON SCIENTIFIC CORPORATION and BOSTON SCIENTIFIC SCIMED, INC., Plaintiffs/Counter-Defendants, v. JOHNSON & JOHNSON, INC., CORDIS CORPORATION, and WYETH Defendants/ Counter-Plaintiffs.	Civil Action No. 07-333-SLR Civil Action No. 07-348-SLR Civil Action No. 07-409-SLR
BOSTON SCIENTIFIC CORPORATION and BOSTON SCIENTIFIC SCIMED, INC., Plaintiffs/Counter-Defendants, v. JOHNSON & JOHNSON, INC., CORDIS CORPORATION, and WYETH Defendants/ Counter-Plaintiffs.	Civil Action No. 07-765-SLR **REDACTED PUBLIC VERSION**

DEFENDANTS/COUNTER-PLAINTIFFS
ANSWERING CLAIM CONSTRUCTION BRIEF

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BSC's apparent aim in formulating its proposed claim constructions was to set up noninfringement or indefiniteness arguments for trial. Its aim should have been to hew to the intrinsic evidence, as Cordis tried to do. Discussions of individual terms are set forth below.

I. THE "POLYMER" LIMITATIONS

A. "Polymer" and "Polymeric"

"polymer"	
Cordis's Proposed Construction	BSC's Proposed Construction
A material formed by polymerization and comprising repeating units of the same or different types of monomers.	A molecule composed of many repeating units of a single monomer.
"polymeric"	
Cordis's Proposed Construction	BSC's Proposed Construction
Containing a "polymer" (previously defined).	Relating to a material comprising a polymer or copolymer.

Claims are supposed to be construed in light of the intrinsic evidence, *taken as a whole*. But BSC asks the Court to base its entire analysis of the term "polymer" on only a single phrase in isolation – the phrase "acrylate-based polymer or copolymer." BSC's argument fails for at least three reasons.[1]

First, there is no disavowal in the specification or other intrinsic evidence that would suggest that the inventors intended to exclude homopolymers from the term "polymer," which ordinarily includes homopolymers and copolymers. *See* D.I. 253, BSC Br. at 15 (acknowledging

[1] The parties' constructions of the term "copolymer" are substantially similar, as discussed in Cordis's Opening Claim Construction Brief. (Case No. 07-409 D.I. 270 at 12.) All citations to the docket are to Case No. 07-409, unless otherwise indicated.

that "[i]n its broadest sense, 'polymer' can refer to all polymeric materials, regardless of the types of monomers used"). For there to be such a disavowal, the inventors would have to have "demonstrated an intent to deviate from the ordinary and accustomed meaning" of the term "by including in the specification expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." *Epistar Corp. v. Int'l Trade Comm'n*, 566 F.3d 1321, 1334 (Fed. Cir. 2009). The use of the phrase "acrylate-based polymers or copolymers" does not come close to the kind of "expressions of manifest exclusion or restriction" that would demonstrate that the inventors intended to exclude all homopolymers from the scope of their invention. To the contrary, the phrase "acrylate-based polymers and copolymers" reinforces that the inventors intended to claim "acrylate-based" polymeric materials broadly, regardless of how this phrase might later be interpreted. BSC also fails to point to any reason why the inventors would have intended their invention to be narrowly limited to homopolymers.

Second, it is well established that claim construction must be determined "in the context of the *entire* patent, including the specification." *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d 1364, 1373 (Fed. Cir. 2005) (emphasis added). In particular, the "court must always read the claims in view of the *full* specification." *SanDisk Corp. v. Memorex Prods., Inc.* 415 F.3d 1278, 1285). Thus, "it is necessary to consider the specification *as a whole*, and to read *all* portions of the written description, if possible, in a manner that renders the patent internally consistent." *Pfizer*, 429 F.3d at 1373 (emphasis added).

Here, as explained in Cordis's Opening Brief, the specification repeatedly uses the term "polymer" to describe *both* homopolymers *and* copolymers, and specifically lists copolymers as examples of the "polymers" that can be used in the claimed invention. *See* D.I. 270, Cordis Opening Br. at 6-7. The patents also include dependent claims specifically reciting copolymers

as examples of the claimed "polymers." *Id.* at 7-8. Moreover, the Patent Examiner specifically used the term "polymer" during prosecution to refer to homopolymers and copolymers. *Id.* at 8-9. The specification, as well as the rest of the intrinsic evidence, *as a whole*, therefore shows that the inventors did not intend to limit the term "polymer" to only homopolymers.

Third, limiting the claimed "polymers" to homopolymers would exclude embodiments that are disclosed in the specification. The specification describes embodiments using a copolymer as the "polymer" for the stent coating. '7286 Patent, A1016, Col. 6, lns. 39-43 (describing "lactone-based...copolyesters," "polycaprolactone-glycolide, and poly (ether-ester) copolymers" as the stent coating); lns. 45-46 (describing "poly(ethylene-vinylacetate)" and "acrylate-based...copolymers" as the "polymer" for the stent coating). Indeed, poly(ethylene-vinylacetate) – a copolymer – is what the inventors ultimately selected for the Cypher stent. As the Federal Circuit has explained, "[w]e normally do not interpret claim terms in a way that excludes disclosed examples in the specification." *Verizon Servs. Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295, 1305 (Fed. Cir. 2007). Thus, the Federal Circuit has rejected narrow constructions of a claim term when it would exclude embodiments specifically described in the specification. *See Abbott Labs. v. Andrx Pharms., Inc.*, 473 F.3d 1196, 1210-11 (Fed. Cir. 2007) (declining to limit term "pharmaceutically acceptable polymer" to "water-soluble hydrophilic polymers" because "that definition would not cover some of the very polymers listed" in the specification); *Pfizer*, 429 F.3d at 1373-76 (refusing to limit the term "saccharides" to sugars because it would exclude embodiments in the specification); *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1369 (Fed. Cir. 2003) (district court's claim construction improperly excluded an embodiment described as an example in the specification).

BSC argues nonetheless that the term "polymer" must be limited to homopolymers because otherwise the term "copolymer" in the single phrase "acrylate-based polymers or copolymers" would be redundant. D.I. 255, BSC Br. at 16. As explained in Cordis's Opening Brief and the declaration of Dr. Mikos, an expert in the area of polymers and biomaterials, there is a perfectly reasonable construction of the phrase "acrylate-based polymer or copolymer" that would not render the term "copolymer" in that phrase redundant. D.I. 270, Cordis Br. at 11; D.I. 272, Mikos Decl. at ¶¶ 43-47. But even if there was some redundancy, it should be limited to that phrase and not be used to limit *all* uses of the term "polymer." Any such redundancy would not be the kind of clear disavowal or other evidence that would require disregarding the clear meaning of the term "polymer" in other contexts based on the intrinsic evidence as a whole. *See Pfizer*, 429 F.3d at 1373 (finding that a single use of the phrase "i.e." in the specification did not override the meaning of the claim term based on the specification as a whole).

The cases cited by BSC do not support its construction. BSC cites *Renishaw PLC v. Marposs Societa per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998), but that case only reinforces the fact that the claims must be construed based on the intrinsic evidence *as a whole*. As the Federal Circuit explained in that case:

> Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction.

Id. at 1250. Here, it is manifestly clear from the specification, claims, and prosecution history that what the inventors actually invented was not limited to homopolymer coatings, but encompassed polymer coatings of both homopolymers and copolymers. BSC also cites to *Mangosoft, Inc. v. Oracle Corp.*, 525 F.3d 1327, 1330-31 (Fed. Cir. 2008), but in that case the

Court rejected a construction that was "beyond the breadth of anything in the claims or the specification." That is clearly not the case with Cordis's proposed construction of the term "polymer" here, which is entirely consistent with the specification and claims. And, in *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1324 (Fed. Cir. 2001), the Court rejected a proposed construction that construed "unambiguous language" in a claim "in a manner inconsistent with its ordinary meaning." Here, by contrast, BSC is the one attempting to construe the term "polymer" in a manner contrary to its ordinary meaning and its usage in the specification.

Finally, BSC's construction of "polymer" is undercut by BSC's admission that the term "polymeric" encompasses both homopolymers and copolymers. The English meaning of the suffix "-ic" is "having the character or form of." (*Merriam-Webster's Collegiate Dictionary* A106.) Thus, "polymeric" simply means "having the character or form of" a polymer. It would be nonsensical to construe "polymeric" to include copolymers while construing "polymer" (the root) to exclude them.[2]

B. "Acrylate-Based Polymer or Copolymer"

"acrylate-based polymer"	
Cordis's Proposed Construction	**BSC's Proposed Construction**
a "polymer" (previously defined) in which all of the monomers are based on the structure of a salt or ester of acrylic acid.	A molecule composed of many repeating units of a single acrylate monomer.

[2] BSC agrees that a "fluorinated polymer" merely requires that the polymer "contains one or more fluorine atoms." The only dispute relates to the meaning of the term "polymer," which is addressed above.

"acrylate-based copolymer"	
Cordis's Proposed Construction	**BSC's Proposed Construction**
a "copolymer" (previously defined) in which at least one of the types of monomers is based on the structure of a salt or ester of acrylic acid.	A molecule comprising many repeated units of a single monomer where at least one of the monomers is an acrylate.
"acrylate-based polymer or copolymer"	
Cordis's Proposed Construction	**BSC's Proposed Construction**
Previously defined.	A molecule comprising many repeating units of a single acrylate monomer, or a molecule comprising many repeating units of at least two different monomers where at least one of the monomers is an acrylate.

BSC argues that Cordis's definition of "acrylate-based polymer or copolymer" is inconsistent with its definition of "fluorinated polymer," and should require only that an acrylate be somewhere within the polymer.[3] D.I. 255, BSC Br. at 17-18. BSC, however, ignores the language itself, which requires that the polymer or copolymer be "acrylate-*based*." This means that an acrylate must form the fundamental part or basis of the molecule.[4] (D.I. 272, Mikos Decl. at 43.) There is no corresponding language in the claim term "fluorinated polymer."

[3] Although the parties dispute the meaning of the phrase "acrylate-based polymer or copolymer," this dispute has no direct outcome on the ultimate issues in this case. The only "acrylate-based" polymer at issue is the polybutyl methacrylate (PBMA) polymer used in both the BSC Promus stent and the Cordis Cypher stent. This is an "acrylate-based polymer" under either party's definition because it includes many repeated units of a single acrylate monomer, butyl methacrylate (BMA). (D.I. 272, Mikos Decl. at 43-44.)

[4] The term "base" when used as a verb means "to serve as a base for," and when used as a noun, means "the fundamental part of something." (*Webster's Third* A1064-A1065.)

II. "BIOCOMPATIBLE"

Cordis's Proposed Construction	BSC's Proposed Construction
Able to perform its function in the body with an acceptable biological response.	Does not elicit any negative tissue reaction or promote mural thrombus formation.

A. 1997 Patents

BSC's construction is taken from a single statement in the specification that "[p]olymers are biocompatible (i.e., not elicit any negative tissue reaction or promote mural thrombus formation) and degradable, such as lactone-based polyesters or copolyesters...." D.I. 255, BSC Br. at 12-14. It is unclear exactly what BSC intends to do with its construction at trial, but it appears BSC may try to argue that it excludes the very polymers expressly described in the specification as "biocompatible." It is undisputed that these polymers produce small, but still acceptable, amounts of inflammation. *See* D.I. 270, Cordis Br. at 15-16.

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BSC itself makes the telling admission that any "foreign object inserted into the body" will cause "some amount of inflammation." (Case No. 07-765, D.I. 262 at 12.) It is well settled that a "claim construction that excludes a preferred embodiment" is "rarely, if ever, correct." *Pfizer*, 429 F.3d at 1374. The Court should therefore adopt Cordis's proposed construction, which is a straightforward expression of the ordinary meaning of "biocompatible" and is consistent with the patent as a whole. *See Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1360 (Fed. Cir. 2008) (purpose of claim construction is "explaining and defining terms in the claims" as an "aid to the decision-maker").

BSC's entire argument rests on the premise that the "i.e." language in the specification is an express definition provided by the inventors. The Federal Circuit, however, has made clear that a court should not equate an "i.e." phrase with an express definition of a claim term unless doing so is consistent with "the context of the entire patent." *Pfizer*, 429 F.3d at 1373. In *Pfizer*, the Federal Circuit rejected the argument that the phrase "saccharides (i.e. sugars)" in the specification limited saccharides to sugars, because the other portions of the specification gave examples of saccharides that were not sugars. *Id.* at 1373-74. The Court found that the infringer's exclusive reliance on the "i.e." phrase was improper because "it ignores the fact that the person of ordinary skill in the art is deemed to have read the claim term in the context of the *entire* patent." *Id.* at 1373 (emphasis added). Rather than focusing just on the use of the term "i.e.," "it is necessary to consider the specification *as a whole*, and to read *all* portions of the written description, if possible, in a manner that renders the patent internally consistent." *Id.* (emphasis added).

Here, as explained in Cordis's opening brief, the specification *as a whole* demonstrates that the inventors gave the term "biocompatible" its ordinary meaning. The specification repeatedly describes examples of "biocompatible" polymers that were known in the art to cause at least some minor amount of inflammation. D.I. 270, Cordis Br. at 14-16. During prosecution, the inventors also referred to the Xience/Promus polymer

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Portions of the specification not cited by BSC indicate that the inventors did not intend to use "*i.e.*" to signify a specialized definition, but rather to mean "for example." The specification refers to "[c]ell derived growth factors ... released from platelets (i.e., PDGF)," or platelet derived growth factor. ('7286 patent, A1014-A1015 Col. 2:65-3:1.) PDGF, however, is only

one example of many cell-derived growth factors released from platelets.[5] Adams et al., Pathophysiology of Atherosclerosis: Development, Regression, Restenosis, *Current Atherosclerosis Reports* 2000; 2:251-258 (A1236). "When a patentee acts as his own lexicographer in redefining the meaning of particular claim terms away from their ordinary meaning, he must *clearly express that intent* in the written description." *Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364, 1371 (Fed. Cir. 2005) (emphasis added). The Federal Circuit has "repeatedly emphasized that the statement in the specification must have sufficient clarity to put one reasonably skilled in the art on notice" that the inventor intended to provide a specialized definition. *Id.* The "i.e." statement here fails that standard.

BSC points on page 13 of its brief to a statement in the "Summary of the Invention," but the portion BSC quotes merely refers to characteristics of a hypothetical "ideal coating material," rather than defining "biocompatible," or even describing the actual polymers that the inventors contemplated for use on the stent. '7286 patent, A1015 Col. 3:50-60. BSC further refers to a declaration submitted by Dr. Mikos during the reexamination of the 1997 Patents (D.I. 255, BSC Br. at 14), but that merely uses the term "biocompatible" in its ordinary and customary manner, as reflected in Cordis's proposed construction.

Finally, there is no merit to BSC's argument that Cordis's claim construction of "biocompatible," which reflects the ordinary meaning of the term in the art, is indefinite. D.I. 255, BSC Br. at 13. Persons of ordinary skill can readily determine whether specific materials are biocompatible by running standard tests known in the art; indeed the FDA has published

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[5] The specification also refers to "[c]ell derived growth factors ... released ... directly from SMC [smooth muscle cells] (i.e. BFGF)." ('7286 patent, A1014-A1015 Col. 2:65-3:3.) Smooth muscle cells, however, also release a number of cell derived growth factors, other than BGFG. *See* Crowley et al., *Multiple growth factors are released from mechanically injured vascular smooth muscle cells*, Am J Physiol Heart Circ Physiol 269: H1641-H1647, 1995 (A1042-A1048).

guidelines for determining biocompatibility.[6] Abbott used such tests to persuade the FDA that the Xience/Promus stent was "biocompatible." A1072-A1094.

B. '662 Patent

BSC proposes the same construction of "biocompatible" for the '662 patent as for the 1997 patents. D.I. 263, BSC Br. at 33. The '662 patent specification, however, does ***not*** contain the "i.e." phrase which is the sole basis for BSC's construction of "biocompatible" in the 1997 patents. BSC gives no explanation for why this phrase, which appears nowhere in the '662 specification, should be considered as an express definition of "biocompatible" in that patent. Indeed, BSC provides no basis whatsoever in the '662 patent's intrinsic evidence for its proposed construction. Accordingly, the ordinary meaning of biocompatible, as reflected in Cordis's proposed construction, should be adopted.

III. "AFFIXED," "APPLIED" AND "ONTO" LIMITATIONS

A. Applied Thereto (1997 Patents)

Cordis's Proposed Construction	BSC's Proposed Construction
Put thereon	To the extent not indefinite: Brought into direct contact with the stent surface.

BSC asks the Court to read a limitation into the claim by construing "applied" to mean "applied directly to the stent surface." D.I. 255, BSC Br. at 26-27. There is nothing in the claim language to support such a construction. If the inventors had intended the claim to mean

[6] *See, e.g.*, Guidance for Industry and FDA Staff, Non-Clinical Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems; published by the Interventional Cardiology Devices Branch, Division of Cardiovascular Devices, Office of Device Evaluation on January 13, 2005 (A1095-A1111.)

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"applied directly to the surface," they could have put that language in the claim. They did not do so, and the Court should not read it in.

BSC further argues that "applied" should mean "applied directly to the stent surface" because that is the embodiment described in the specification. D.I. 255, BSC Br. at 26-27. But the Federal Circuit has "expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005). There is no language of exclusion or disavowal in the specification that would show an intent to exclude coatings which are not applied directly to the surface of the stent.

BSC also points to language in the specification stating that the coating must "adhere strongly to the metal stent." D.I. 255, BSC Br. at 26. But something need not be in direct contact with a surface in order to adhere strongly to it. For example, even though wallpaper is applied to a wall using glue rather than by direct contact, it adheres strongly to the wall, as anyone who has tried to remove it can attest.[7]

IV. "CARRIER"

Cordis's Proposed Construction	BSC's Proposed Construction
Material that carries the drug.	A therapeutic agent-containing material co-formulated with the therapeutic agent.

Cordis's definition of "carrier" is based on the plain meaning of the term. BSC, by contrast, attempts to read in a limitation from the specification that the material carrying the drug is also "co-formulated" with the drug. BSC's only support for reading in this limitation is that it

[7] BSC's support for its proposed construction of "affixed" in the '662 patent largely references its arguments relating to the term "applied" in the 1997 patents, and suffers from similar infirmities.

appears in the preferred embodiment. D.I. 263, BSC Br. at 22. But there is no language of exclusion or disavowal in the specification that would manifest an intent to exclude carriers which are not co-formulated with the drug. Because it is error to limit claims to a preferred embodiment, BSC's proposed construction is improper. *Phillips*, 415 F.3d at 1323.

V. "COATING"

Cordis's Proposed Construction	BSC's Proposed Construction
Covering layer(s)	To the extent not indefinite: A distinct covering layer of a particular composition.

BSC argues that its construction is correct because "the specification discloses only a stent with a single, distinct covering layer as a coating." D.I. 255, BSC Br. at 24. BSC is again attempting to limit the claims to the embodiment disclosed in the specification, which is improper and should be rejected. *See Phillips*, 415 F.3d at 1323. The specification nowhere limits the invention to stents with only a one-layer coating.

BSC points to a statement in the specification noting that the "ideal coating material" should be "as thin as possible so as to minimize the increase in profile." D.I. 255, BSC Br. at 25. The claimed invention, however, is not limited to such an "ideal coating material." Moreover, the thickness of the overall coating is not necessarily a function of how many layers it has. For example, a stent with two thin layers can have a thinner coating than a stent with one thick layer. Abbott and BSC tout their stent as having a thin coating even though it contains more than one layer. *Xience Patient Information Guide* at A1185; *Promus Patient Information Guide* at A1132.

BSC's citation to the declaration of Dr. Mikos during the reexamination of the 1997 patents does not support its construction. The quoted statement merely points out that the Ding reference does not disclose the use of a fluorinated polymer mixed with effective amounts of a

rapamycin drug. Dr. Mikos never remotely suggested that the term "coating" in the claims did not or could not refer to multiple layers. Indeed, the Ding patent itself uses the term "coating" to refer to multiple layers. *See, e.g.*, A1129 3:28-31; 4:12.

VI. THE "ANALOG" TERMS[8]

A. "Macrocyclic Lactone Analog" (of Rapamycin)

Cordis's Proposed Construction	BSC's Proposed Construction
A compound structurally similar to sirolimus having the same macrocyclic lactone ring structure which is capable of inhibiting both the inflammatory response known to occur after arterial injury and stent implantation, as well as the smooth muscle cell hyperproliferative response.	To the extent not indefinite: A macrocyclic lactone molecule with a structure similar to rapamycin (as defined)

In arguing for its proposed construction of the term "macrocyclic lactone analog" (of rapamycin), BSC focuses on generalized dictionary definitions of the term "analog." D.I. 263, BSC Br. at 8-11. These definitions, however, are not specific to any particular molecule, or even to drugs, but relate to chemical compounds generally. They have little bearing on what a person of ordinary skill would have understood a "macrocyclic lactone analog" of *rapamycin* to be in the inventions of the 1997 patents.

BSC ignores the intrinsic evidence, which demonstrates that the inventors considered the functional properties of rapamycin to be critical to their invention. As explained in Cordis's opening brief, the specification emphasizes these properties in describing how a rapamycin drug reduces neointimal proliferation and inflammation. D.I. 270, Cordis Br. at 25-26. BSC also ignores the fact that during prosecution the inventors defined "analogs" as molecules having

[8] The construction of the term "rapamycin" in the patents-in-suit is addressed in Cordis's opening brief.

"similar methods of action," and distinguished paclitaxel and its analogs from rapamycin and its analogs on the basis that "[t]he method of action of these two classes of drugs is quite different." *Id.* at 26-27.

BSC provides no convincing basis for overriding this intrinsic evidence. BSC argues that Cordis's functional language would be superfluous because certain claims also state that the drug must be "present in an amount effective to inhibit neointimal proliferation." The "amount effective" limitation, however, concerns the *amount* of drug present on the stent. It would not be rendered superfluous by Cordis's proposed construction which includes key functional characteristics of *the drug itself.*

As Dr. Sabatini explains, a person of ordinary skill would have known at the time of filing that the binding regions of the molecule, are located in the macrocyclic ring, and that sirolimus's binding properties are what led to its antiproliferative and anti-inflammatory effects. D.I. 270, Cordis Br. at 27-28. A person of ordinary skill would therefore have understood a "macrocyclic lactone analog" to preserve this macrocyclic lactone ring. (D.I., 273, Sabatini Decl. at ¶ 43-44.) BSC provides no evidence to the contrary.

B. "Macrocyclic Triene Analog" (of Rapamycin)

Cordis's Proposed Construction	BSC's Proposed Construction
A compound structurally similar to sirolimus having the same macrocyclic triene ring structure which is capable of inhibiting both the inflammatory response known to occur after arterial injury and stent implantation, as well as the smooth muscle cell hyperproliferative response.	To the extent not indefinite: A macrocyclic triene molecule with a structure similar to rapamycin (as defined).

BSC does not dispute that the specification of the '662 patent describes the key functional properties of rapamycin as being important to the invention, or that a person of ordinary skill

would so understand based on the specification. BSC merely argues that functional language in Cordis's proposed definition is "unnecessary" because functional properties are also in the definition of "rapamycin." D.I. 263, BSC Br. at 32-33. But the term "macrocyclic triene analog" (of rapamycin) is broader than "rapamycin" alone, and therefore the functional properties are not superfluous or unnecessary in the construction of this term.

As in the case of the term "macrocyclic lactone analog," a person of ordinary skill would understand that the binding regions of sirolimus are located in the macrocyclic triene ring and the macrocyclic triene ring structure should be maintained intact in a "macrocyclic triene analog." *See* D.I. 270, Cordis Br. at 29.

VII. THE "INHIBIT" AND "AMOUNT EFFECTIVE" LIMITATIONS

"an amount effective to inhibit neointimal proliferation"	
Cordis's Proposed Construction	**Boston Scientific's Proposed Construction**
An amount that works to reduce neointimal proliferation	To the extent not indefinite: an amount sufficient to stop neointimal proliferation.
"present in a therapeutically beneficial amount to inhibit neointimal proliferation"	
Present in an amount that is enough to help the patient by reducing neointimal proliferation	To the extent not indefinite: an amount sufficient to stop neointimal proliferation.
"present in an amount effective to inhibit neointimal proliferation"	
An amount that works to reduce neointimal proliferation	To the extent not indefinite: an amount sufficient to stop neointimal proliferation.

As Cordis explained in its opening brief, the intrinsic evidence and the ordinary meaning both demonstrate that "inhibiting" neointimal proliferation means reducing neointimal

proliferation. Cordis Br. at 30-31. BSC's argument that this term requires that neointimal proliferation be "stopped" lacks support and should be rejected.

BSC cites only a single dictionary (the *Merriam-Webster Dictionary*), but even that dictionary does not support its construction. D.I. 255, BSC Br. at 27. Its cited definition is "hold in check: restrain," *id.*, which does not require a complete stopping. To the contrary, "restrain" means "to limit, restrict or keep under control." *See Merriam-Webster Dictionary* A1245. A dog that is "restrained" is not necessarily immobile.

BSC next argues that the specification defines "inhibit" to mean "prevent." But the portions of the specification BSC cites do not demonstrate a clear intent to expressly define "inhibit" as "prevent." Moreover, even if they did, these portions also demonstrate that the inventors used the term "prevent proliferation" to mean "reduce proliferation," not stop it completely. For example, the specification states that "Marx et al. ... have demonstrated that rapamycin prevents proliferation of both rat and human SMC in vitro." A1016 5:43-45. But the Marx article reported a small amount of cell proliferation in cells treated with sirolimus, indicating that cell proliferation was not stopped completely. (D.I. 271, Rogers Decl. at 32.)

BSC also takes out of context a sentence in a declaration of Dr. Mikos during the reexamination, stating that to be successful a stent "had to be efficacious in adequately preventing smooth muscle cell proliferation." D.I. 255, BSC Br. at 28. In this portion of the declaration, however, Dr. Mikos was providing background information on "[n]umerous publications" describing efforts to develop a drug-eluting stent in the mid-1990s, not defining the scope of the claimed inventions or the meaning of the term "inhibit." Moreover, Dr. Mikos's use of the term "adequately" makes it clear that he meant that a stent should prevent enough of the

smooth muscle cells from proliferating in order to have a meaningful impact on restenosis, not that *all* cells must be stopped from proliferating.

BSC also misconstrues a section of Dr. Mikos's reexamination declaration describing the remarkable results of the First-in-Man trial of the Cypher stent as somehow imposing a claim limitation in the 1997 patents that the stent have "zero restenosis." D.I. 255, BSC Br. at 28-29. But there is no support for such a limitation anywhere in Dr. Mikos's declaration or in the intrinsic evidence, and BSC points to none. The claims merely require that the stent "inhibit neointimal proliferation," and make no reference to the "zero restenosis" result achieved in the First-in-Man trial of Cypher.

VIII. "HUMAN POPULATION"

"human population"	
Cordis's Proposed Construction	Boston Scientific's Proposed Construction
a group of human patients that are candidates for coronary stent therapy and would be a suitable group for testing in a clinical trial for stents	To the extent not indefinite: A class of people distinguished by particular traits or characteristics.

BSC's construction of the term "human population" is based on general purpose dictionary definitions rather than the intrinsic evidence. The intrinsic evidence supports Cordis's definition.

The '662 patent and claims are not directed to humans generally but rather to specific humans – those who are candidates for coronary stent therapy. As explained in Cordis's opening brief, the '662 patent specifically describes angiographic data obtained in a clinical trial of sirolimus-eluting stents in humans, and cites references describing clinical trials of stents. D.I. 270, Cordis Br. at 32-33. The claims also describe angiographic results that are generally only

obtained in clinical trials of stents. *Id.* at 33-34. And, during prosecution, Cordis referenced a clinical trial of the Xience/Promus stent as an example of the claimed "human population." *Id.* at 33. BSC ignores this intrinsic evidence.

BSC argues that Cordis's proposed construction would be indefinite because it "leaves undecided what makes a group 'suitable' for testing in a clinical trial, and who decides suitability." D.I. 255, BSC Br. at 36. But as Dr. Rogers explained, persons of ordinary skill in 2001 would have been familiar with the design of clinical trials and the selection criteria that were used in such trials, and would have understood how to select a suitable population for testing a drug-eluting stent in the coronary arteries of patients. (D.I. 271, Rogers Decl. at ¶¶ 23-24.) By 2001 numerous clinical trials of stents had been conducted. (*See, e.g.*, Fischman et al., A Randomized Comparison of Coronary-Stent Placement and Balloon Angioplasty in the Treatment of Coronary Artery Disease, *New Engl J Med*, 1994; 331:496-501 (A1246-A1251); Serruys et al., A Comparison of Balloon-Expandable-Stent Implantation with Balloon Angioplasty in Patients with Coronary Artery Disease, *New Engl J Med* 1994; 331:489-495 (A1252-A1258); Sousa et al., Sustained Suppression of Neointimal Proliferation by Sirolimus-Eluting Stents, *Circulation*, 2001; 104:2007-2011.) BSC presents no contrary evidence.

Finally, BSC argues that Cordis's construction does not "make sense" because "[t]he purpose of the stent is to treat patients, not generate clinical trials." D.I. 255, BSC Br. at 36-37. The claims, however, describe certain angiographic parameters, including late loss and percent diameter stenosis which are generally only measured in patients in a clinical trial. A person of ordinary skill would therefore understand that patients in a clinical trial for stents would be the appropriate population in which to test the claimed angiographic parameters.

IX. OTHER LIMITATIONS

A. "Stent"

Cordis's Proposed Construction	Boston Scientific's Proposed Construction
A tube-shaped mesh device used to treat certain forms of cardiac disease.	A device for providing support for a lumen in the body.

BSC argues that Cordis's proposed construction is "unnecessarily limited to cardiac disease." D.I. 255, BSC Br. At 23. The 1997 patents, however, are entirely directed to the treatment of cardiac disease, specifically through percutaneous transluminal coronary angioplasty (PTCA) procedures.

BSC also cites to a definition of "stent" in an unrelated district court cause involving different patents and different parties. In previous litigation between BSC and Cordis, however, the Federal Circuit adopted the same definition of "stent" as Cordis proposes here, in the context of a patent for a stent for treating cardiac disease. *See Jang v. Boston Scientific Corp.*, 532 F.3d 1330, 1332 (Fed. Cir. 2008).

B. "Mixture"/"Mixture Thereof"/ "Mixed Together"/"Blend Thereof"

"Mixture"/"Mixture Thereof"/"Mixed Together"	
Cordis's Proposed Construction	BSC's Proposed Construction
"Mixture" means combination; "mixture thereof" means combination of the foregoing; "mixed together" means combined together.	To the extent not indefinite: "mixture" and "mixture thereof" mean a composition in which substances are combined and intermingled; "mixed together" means combined and intermingled.

"Blend Thereof"	
Cordis's Proposed Construction	BSC's Proposed Construction
A mixture of two or more of the foregoing.	A composition of combined and intermingled substances.

BSC once again attempts to limit the claims to the preferred embodiment in the specification. BSC argues that the claims should be limited to "intermingled" mixtures because in the specification "the only description of the 'comixture' of a drug and its polymeric carrier involves mixing them in solution and then applying the solution to the stent." D.I. 255, BSC Br. at 21-22. However, it is error to limit the claims to the preferred embodiment described in the specification. *Phillips*, 415 F.3d at 1323. BSC cites nothing in the specification suggesting that the inventors intended to limit their invention to mixtures that were "intermingled." Nor does BSC point to any clear disavowal of other types of mixtures.

C. "Provides a Controlled Release of [X] Over a Period of Several Weeks"

Cordis's Proposed Construction	BSC's Proposed Construction
Releases X gradually, where some drug is released during each of several weeks.	To the extent not indefinite: [X] is discharged in a controlled manner over a period of more than one week and up to six weeks.

As Cordis explained in its opening brief, there is nothing in the intrinsic evidence that would require that 100% of the drug be discharged over a period of several weeks. D.I. 270, Cordis Br. at 36-37. To the contrary, the prosecution history demonstrates that the inventors intended this phrase to encompass stents that did not release 100% of the drug over several weeks, like the Xience/Promus stent. Cordis Br. at 36. BSC cites no evidence to support such a requirement.

BSC also argues that Cordis's definition of "several" is indefinite. The term "several," like the term "about," is a term that "avoids a strict numerical boundary." *See Ortho-McNeil Pharmaceutical, Inc. v. Caraco Pharmaceutical Labs, Ltd.*, 476 F.3d 1321, 1327-28 (construing "about"). Courts have routinely interpreted such terms in a manner similar to Cordis's proposed construction here, without finding them indefinite. *See Ortho-McNeil* at 1327-28; *Merck & Co., Inc.*, 395 F.3d at1369.

D. "In-Stent Late Loss"/"In-Stent Diameter Stenosis"

"In-Stent Late Loss"	
Cordis's Proposed Construction	**BSC's Proposed Construction**
The loss of lumen diameter, calculated by taking the smallest lumen diameter, after implantation, anywhere within the stent, and then subtracting the smallest lumen diameter, at a specified time (such as one year) following implantation, anywhere within the stent.	To the extent not indefinite: The minimal luminal diameter (determined by a specific protocol) within the stent immediately following implantation minus minimal lumen diameter (determined by a specific protocol) within the stent at a specified time following implantation.
"In-Stent Diameter Stenosis"	
Cordis's Proposed Construction	**BSC's Proposed Construction**
100 X [1-(minimal lumen diameter / reference vessel diameter)].	To the extent not indefinite: 100 X [1 – (minimal lumen diameter determined by a specific protocol / reference vessel diameter determined by a specific protocol)].

BSC argues that its construction is superior because it "clarifies that the first measurement must be taken immediately following implantation." D.I. 255, BSC Br. at 34-35. But nothing in the claims or specification requires a precise time for measuring the minimal

lumen diameter. Any clinically reasonable time for measuring the minimal lumen diameter is covered by the claims.

E. "Quantitative Coronary Angiography"

Cordis's Proposed Construction	BSC's Proposed Construction
A test to measure the lumen diameter of coronary vessels.	To the extent not indefinite: An analytical technique employing particular specified hardware and software, and technician assumptions.

BSC criticizes Cordis's proposed construction because it "ignores QCA protocols entirely." D.I. 255, BSC Br. at 35-36. But the particular protocol to be used for the QCA procedure is not critical to the claimed invention, and appropriate QCA protocols were well known in the art. (D.I. 271, Rogers Decl. at ¶¶ 18-19). Neither the specification nor the claims require any specific protocol. Nor was there any need for the inventors to put a specific protocol in the specification or claims, because "a patentee preferably omits from the disclosure any routine technology that is well known at the time of application." *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1254 (Fed. Cir. 2004). A person of ordinary skill would have understood that any clinically acceptable protocol could be used. (D.I. 271, Rogers Decl. at ¶ 17-18.)

BSC's argument that failure to specify the particular QCA protocols would "effectively read[] the limitation out of the claims" also lacks merit. D.I. 255, BSC Br. at 35-36. The claims require that in-stent late loss and percent diameter stenosis be measured by a particular technique – QCA – rather than other techniques. The requirement that QCA be used is meaningful and is therefore a claim limitation. The specific QCA protocol is not.

F. "About"

Cordis's Proposed Construction	BSC's Proposed Construction
Approximately.	Very close to.

BSC does not dispute that the ordinary meaning of the term "about" is "approximately," as explained in Cordis's opening brief. D.I. 270, Cordis Br. at 38-39. BSC argues that the specific way that "about" is used in the '662 patent compels a narrower definition. BSC is mistaken.

BSC first argues that "about" should be construed narrowly because two of the values tested in rabbits – 196 μg and 197 μg – are very close to one another. Second, BSC argues that "about" should be given a narrow construction because the claimed values for in-stent late loss and percent diameter stenosis are close to the values obtained by adding the mean and standard deviation for the First-in-Man trial. Neither, however, qualifies as an express definition of the term "about," or clearly expresses an intent by the inventors to redefine the ordinary meaning of the term. *See Merck*, 395 F.3d at 1371.

X. CONCLUSION

For the foregoing reasons, and those set forth in Cordis's Opening Claim Construction Brief, Cordis respectfully requests that its proposed constructions be adopted.

ASHBY & GEDDES

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CERTIFICATE OF SERVICE

I hereby certify that on the 19th day of October, 2009, the attached **REDACTED PUBLIC VERSION OF DEFENDANTS/COUNTER-PLAINTIFFS' ANSWERING CLAIM CONSTRUCTION BRIEF** was served upon counsel of record at the address and in the manner indicated:

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